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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,938

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EXAMINER

SISSON, BRADLEY L

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

04/04/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/564,938

Applicant(s)

EKSTROM ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 71-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 November 2009 has been entered.

Drawings

2. The drawings were received on 27 November 2009. These drawings are not acceptable.
3. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the replacement sheets have been found to comprise duplication of figures. Specifically, Replacement Sheet 3 comprises FIGS. 2D – 2F; Replacement Sheet 5 comprises FIGS. 2G - 2I, and Replacement Sheet 4 comprises FIGS. 2D – 2I.
4. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 71-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

7. Claim 71 is the sole independent claim pending. For convenience, claim 71 is reproduced below.

71. (new) A method for affinity capturing and concentration of biomolecules, comprising the steps of:

a) providing a plate that fits into Mass Spectrometry instruments, the plate comprises an array of units, each unit comprises an inlet at one side connected to a compartment with an outlet at opposite side of the inlet, said outlet having an analysis zone, said unit enabling fluid flow through from the inlet to the outlet by the use of pressure and allowing biomolecules to be concentrated in said analysis zone present in the area of said outlet;

b) adding a capturing medium having affinity to one type of biomolecules, to one inlet of a unit and allowing said capturing medium to enter said compartment and loading a sample comprising biomolecules to the same unit as said capturing medium and allowing said sample to enter said compartment and allowing said capturing medium to bind to said biomolecules in said sample or mixing said capturing medium having affinity to one type of biomolecules with said sample comprising said biomolecules and then adding the mixture to one inlet of a unit;

c) allowing said sample to pass through said compartment and out from said outlet;

d) applying a washing step to said unit;

e) eluting said biomolecules from said capturing medium to said analysis zone;

and

f) allowing said biomolecules in said analysis zone to dry.

8. Attention is directed to MPEP 904.01.

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The breadth of the claims in the application should always be carefully noted; that is, the examiner should be fully aware of what the claims do not call for, as well as what they do require. During patent examination, the claims are given the broadest reasonable interpretation consistent with the specification. See *In re Morris*, 127 F.3d 1048, 44 USPQ2d 1023 (Fed. Cir. 1997). See MPEP § 2111 - § 2116.01 for case law pertinent to claim analysis.

9. It is noted with particularity that narrowing limitations found in the specification cannot be inferred in the claims where the elements not set forth in the claims are linchpin of patentability. In *re Philips Industries v. State Stove & Mfg. Co, Inc.*, 186 USPQ 458 (CA6 1975). While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into the claims. On the contrary, claims must be interpreted as broadly as their terms reasonably allow. See *Ex parte Oetiker*, 23 USPQ2d 1641 (BPAI, 1992).

As presently worded, the method of claim 71 requires one to utilize a “plate” that has a series of “units” that are in an array. “[E]ach unit comprises an inlet at one side connected to a compartment with an outlet at opposite side of the inlet, said outlet having an analysis zone, said unit enabling fluid flow through from the inlet to the outlet by the use of pressure and allowing biomolecules to be concentrated in said analysis zone present in the area of said outlet.”

10. In accordance with the method, one is to:

- a. Add a capturing medium having affinity to one type of biomolecules, to one inlet of a unit and allowing said capturing medium to enter said compartment
- b. Load a sample comprising biomolecules to the same unit as said capturing medium and allowing said sample to enter said compartment, and either
- c. Allow said capturing medium to bind to said biomolecules in said sample or

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- d. Mix said capturing medium having affinity to one type of biomolecules with said sample comprising said biomolecules and then add the mixture to one inlet of a unit
- e. Allowing said sample to pass through said compartment and out from said outlet
- f. Washing said unit
- g. Eluting said biomolecules from said capturing medium to said analysis zone; and
- h. Allowing said biomolecules in said analysis zone to dry.

11. As presently worded, it is not possible to achieve steps e) through f) as it requires the sample mixture to be subjected to a reverse flow from the “compartment” back into the “inlet” of the unit, all the while steps g and h. require the sample to be flowing in the opposite direction.

12. Such bidirectional sample mixture flow is not recited and no means for achieving same are disclosed. Similarly, the disclosure does not disclose how one is to separate the biomolecule from the “medium having affinity to one type of biomolecule” when such is in the “inlet.”

13. It is further noted that step “e” requires the sample to pass “through said compartment and out from said outlet” which is next subjected to a washing step. If the sample is “out from said outlet, it is no longer in the outlet, which comprises the analysis zone. Consequently, steps g and h, identified above, cannot be achieved, as the components are no longer there.

14. In short, the method as claimed is considered to be inoperable. Given that it is not possible to enable a method that is inoperable, claims 71-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Claim Rejections - 35 USC § 101

15. 35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

16. Claims 71-77 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. As set forth above, the recited method steps have been construed as requiring the sample to be flowed in reverse from the “compartment” to the “inlet” and not to the “outlet.” Additionally, the claimed method has been construed as requiring the mixture to be passed, under pressure, completely out of the device. Such language would proscribe one from ever achieving “eluting said biomolecules from said capturing medium to said analysis zone,” much less “allowing said biomolecules in said analysis zone to dry.”

17. For the above reasons, and in the absence of convincing evidence to the contrary, claims 71-77 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571)272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner, Art Unit 1634